UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RYMED TECHNOLOGIES, INC. and DENISE MACKLIN,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
ICU MEDICAL, INC.,	)	
	)	
Defendant.	)	
**********		**No.: 3:10-01067**
ICU MEDICAL, INC.,	)	**Judge Sharp**
	)	
Counter-claimant,	)	
	)	
v.	)	
	)	
RYMED TECHNOLOGIES, INC.,	)	
	)	
Counter-defendant.	)	

MEMORANDUM

RyMed Technologies, Inc. ("RyMed") and ICU Medical Inc. ("ICU") are competitors in the manufacture and sale of needle-free intravenous connectors. Thus far, they have waged wars on various fronts, including a case in the District of Delaware involving alleged patent infringement, and a case in the Central District of California alleging false advertising and trademark invalidity. With not even a mini-surrender in the offing, and more fighting to be done, the parties bring the battle to this Court raising a host of claims relating to allegations that their competitor made false and misleading statements.

Pending before the Court are numerous motions, including RyMed's Partial Motion to Dismiss (Docket No. 41); ICU's Objections to and/or Motion to Strike Certain Evidence (Docket

Nos. 119 & 128); RyMed's Motion for Partial Summary Judgment (Docket No. 85); ICU's Motion for Summary Judgment on Counts II and III of the Second Amended Complaint (Docket No. 78); RyMed's Motion for Partial Summary Judgment (Docket No. 85); ICU Medical Inc.'s Motion for Summary Judgment on First Amended Counterclaims and Counts I and IV of RyMed's Second Amended Complaint (Docket No. 81); and RyMed's Motions for Review (Docket No. 147) and to Stay (Docket No. 148). Those motions have been fully briefed by the parties.

I. INTRODUCTION

Needle-free connectors, like those at issue in this case, are used for the intravenous delivery of fluids and medications to healthcare patients. Such connectors are often characterized as having negative, positive or neutral displacement (or reflux), determined by the direction and flow of fluid when a luer, or syringe, is disconnected from the needle-free connector. With "negative" displacement connectors, blood refluxes away from the patient into the catheter when a luer is disconnected from the needle-free connector, if the line is not clamped before syringe removal.

Because of concerns over the risk of clot formation from blood reflux, and the incidence of certain catheter-related blood stream infections (CRBSIs), manufacturers developed "neutral fluid displacement" connectors that minimize blood or fluid reflux in the catheter during disconnection. By minimizing reflux, these connectors reduce the occurrence of blood clots, and permit the use of a saline only flush. Connectors marketed as "neutral" include ICU's MicroCLAVE® and RyMed's InVision-Plus®, both of which are front and center in this lawsuit.

II. RYMED'S PARTIAL MOTION TO DISMISS

In the patent dispute in the District of Delaware, a jury returned a verdict finding, among other things, that RyMed's InVision-Plus® connectors infringe ICU's patents. In response to a

Motion for Judgment as a Matter of Law and for New Trial, Judge Leonard P. Stark found there to be sufficient evidence to support the verdict of infringement at least with respect to ICU's Patent No. 5,837,862, but also ruled that a new trial was warranted with respect to some of the other infringement claims.

In its First Amended Counterclaims in this case, ICU alleges that RyMed has made deceptive expressions about the effects of the patent case. Those expressions include that (1) Rymed's customers "will not be held liable for anything regarding RyMed's dispute with ICU Medical"; (2) ICU cannot collect royalties or damages from RyMed's customers at the same time that it recovers from RyMed; (3) "upon RyMed's payment of royalties, RyMed's customers are not liable for any royalties or damages on the same product¨; and (4) "ICU Medical's U.S. patents on the CLAVER and MicroCLAVER are almost all expiring this year."

According to ICU, RyMed's opinions of the potential legal effect of the jury verdict in the Delaware action are unfair and deceptive because RyMed omits to tell its customers that they could be considered infringers under the law, that they could potentially be jointly and severally liable for infringement, and that they could be exposed to infringement liability if RyMed is unable to pay any ultimate judgment assessed in Delaware. ICU seeks injunctive relief requesting that RyMed be prohibited from "[m]aking false and misleading representations concerning the effect of the patent infringement jury verdict in the Delaware Action on purchasers/users of the infringing RYMED InVision-Plus®." (Amended Answer and Counterclaims, Docket No. 40 at 53).

RyMed argues that ICU's counterclaim relating to the patent case should be dismissed for three reasons. First, dismissal is warranted pursuant to Fed. R. Civ. P. 12(b)(6), because statements of opinion regarding pending litigation cannot form the basis of a Lanham Act or TCPA claim.

Second, dismissal is appropriate because the claims are not ripe for review inasmuch as no final judgment has been entered in the Delaware action. Third, and alternatively, this Court should not rule on the claims because the "proper venue" for such claims is in Delaware where the patent dispute is pending, as that court is "better suited to hear such claims based on the legal ramifications of its own proceedings and rulings." (Docket No. 42 at 3).

In its reply brief, ICU makes clear that its claim relating to alleged misrepresentations about the effect of the patent case upon RyMed's customers is grounded solely on the TCPA, not the Lanham Act. Even with that limitation, the Court finds summary judgment is warranted on the statements made in relation to the Delaware action.

"The TCPA was not intended to be a codification of the common law," but, rather, was enacted, "to provide additional, supplementary state law remedies to consumers victimized by unfair or deceptive business acts or practices[.]" Tucker v. Sierra Builders, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005). Because "the TCPA is explicitly remedial, . . . Tennessee courts are therefore required to construe it liberally to protect consumers in Tennessee and elsewhere." Id.

Although the TCPA's focus is on protecting consumers, the fact that ICU is a competitor of RyMed, and not one of its customers, is not an automatic bar to a TCPA claim. See, Affinion Benefits Group, LLC v. Econ-O-Check Corp., 784 F.Supp.2d 855, 879 (M.D.Tenn. 2011) ("As an initial matter, it is clear that Affinion's status as a competitor and a corporation does not deprive it of standing to bring a claim under the TCPA"). Indeed, the TCPA makes "[d]isparaging the goods, services or business of another by false or misleading representations of fact" a deceptive act. Tenn. Code Ann. § 47–18–104(b)(8).

However, RyMed's statements to its customers about the patent litigation, even if false or

misleading, do not disparage ICU's goods, services or business. Recognizing as much, ICU argues that the "proper issue before this Court . . . is limited to whether RyMed's statements in the Patent Infringement letters are actionable under the catch-all provision of the TCPA" which prohibits "[e]ngaging in any other act or practice which is deceptive to the consumer or to any other person." Tenn. Code Ann. § 47–18–104(27).

ICU's contention is, to say the least, interesting. Although ostensibly taking up the mantle on behalf of RyMed's customers, the only way those customers will suffer harm by RyMed's assertion about the patent case is if ICU sues them for infringement, or for a deficiency if RyMed is unable to pay a Delaware judgment. Regardless of ICU's motive, it lacks standing to pursue the TCPA claim insofar as it relates to statements about the patent case, and, in any event, such a claim is unripe.

In PHG Tech., LLC v. St. John Companies, Inc., 459 F. Supp.2d 640 (M.D. Tenn. 2006), the Court was presented with a case in which St. John filed counterclaims against PHG alleging, among other things, that PHG violated the TCPA by making false promises and representations to its customers regarding how they could easily configure software to print medical labels. In finding that St. John lacked standing under the TCPA, Judge Echols wrote:

> The Tennessee General Assembly chose not to include within the TCPA's prohibitions unfair competition or anti-competitive acts. Bennett v. Visa U.S.A. Inc., 198 S.W.3d 747, 754-755 (Tenn. Ct. App.2006); Sherwood v. Microsoft Corp., No. M2000-01850-COA-R9-CV, 2003 WL 21780975 at *33 (Tenn. Ct. App. July 31, 2003). To the extent St. John rests its TCPA claim, not on anti-competitive conduct, but solely on PHG's allegedly false promises and representations to customers in connection with the sale of PHG software, St. John lacks standing to assert such a claim on behalf of PHG customers who may be disenchanted with PHG's products or services. See, Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992); Petty v. Daimler/Chrysler Corp., 91 S.W.3d 765, 768 (Tenn. Ct. App. 2002) (observing standing issue requires careful judicial examination of the allegations made to ascertain whether the particular plaintiff is

> entitled to adjudication of the particular claims asserted). If any customers believe that PHG has engaged in unfair or deceptive practices towards them, then such customers may have standing to bring TCPA claims against PHG, but under the facts presented, St. John does not have standing.

Id. at 645-46.

Likewise in this case, RyMed's statements about the effect of the Delaware action is not anti-competitive conduct, but alleged misrepresentations to customers. Any potential harm is a matter of concern to Rymed's customers, not ICU.

The question of potential harm segues into another reason why dismissal is appropriate: the matter is not ripe for review, even if the claim is properly brought by ICU.

"The ripeness doctrine prevents courts from 'entangling themselves in abstract disagreements' through premature adjudication." Miller v. City of Cincinnati, 622 F.3d 524, 532 (6th Cir. 2010) (citation omitted). "The ripeness doctrine not only depends on the finding of a case and controversy and hence jurisdiction under Article III, but it also requires that the court exercise its discretion to determine if judicial resolution would be desirable under all of the circumstances." Brown v. Ferro Corp., 763 F.2d 798, 801 (6th Cir. 1985). "Three factors guide the ripeness inquiry: '(1) the likelihood that the harm alleged by the plaintiffs will ever come to pass; (2) whether the factual record is sufficiently developed to produce a fair adjudication of the merits of the parties' respective claims; and (3) the hardship to the parties if judicial relief is denied at this stage in the proceedings.'" Berry v. Schmitt, 688 F.3d 290, 298 (6th Cir. 2012) (quoting, Grace Community Church v. Lenox Twp., 544 F.3d 609, 615 (6th Cir. 2008)).[1]

[1] "The first factor reflects the fact that '[[r]ipeness, while often spoken of as a justiciability doctrine distinct from standing, in fact shares the constitutional requirement of standing that an injury in fact be certainly impending.'" Casden v. Burns, 306 Fed. Appx. 966, 971 (6th Cir. 2009) (citation omitted). "The last two considerations, on the other hand, reflect the 'prudential aspect of ripeness.'" Id. at 971-72.

As the first factor suggests, "[r]ipeness becomes an issue when a case is anchored in future events that may not occur as anticipated, or at all." Nat'l Rifle Ass'n of America v. Magaw, 132 F.3d 272, 284 (6th Cir. 1997). Thus, "[i]n undertaking a ripeness analysis," a court must "pay particular attention to the likelihood that the harm alleged by plaintiffs will ever come to pass." United Steelworkers of America, Local 2116 v. Cyclops Corp., 860 F.2d 189, 194 (6th Cir. 1988).

Although "[o]ne does not have to await consummation of threatened injury to obtain preventive relief," Blum v. Yaretsky, 457 U.S. 991, 1000 (1982), and there is no requirement of "inevitability," the Sixth Circuit "has held that a claim is ripe when it is 'highly probable' that the alleged harm or injury will occur." Casden, 306 Fed. Appx. at 972. That likelihood is far from evident here where final resolution of the Delaware litigation is still very much up in the air (even though Judge Stark upheld the jury's verdict that RyMed's products infringe at least the `862 patent), and where harm will only arise if (1) ICU obtains a damages award that exceeds RyMed's ability to pay; and (2) ICU seeks to enforce its patents against RyMed's customers as co-infringers.

Additionally, there has been no showing of any hardship in not allowing the claims related to the statements about the Delaware action to go forward at this time. If, in fact, said statements eventually cause harm, that is something which can be addressed at that time, presumably by Rymed's customers, not ICU.

Accordingly, RyMed's Partial Motion to Dismiss will be granted.

III. ICU'S OBJECTIONS AND MOTION TO STRIKE

In support or its Motion for Partial Summary Judgment and in response to ICU's Motion for Summary Judgment, RyMed has submitted affidavits or declarations from Michael G. Abelow,

Denise Macklin, D. Scott Chase, Dana W. Ryan, James Kaiser, and David P. Gordon. ICU has filed objections (or moved to strike) more than 50 statements made in those affidavits and declarations.

Under Rule 56, as revised by the December 1, 2010 amendments, "[a] party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2). "In some respects, the 2010 amendment to Rule 56 works a sea change in summary judgment procedure and introduces flexibility . . . in place of the bright-line rules that . . . obtained previously," including Rule 56(e)'s "unequivocal direction that documents presented in connection with a summary judgment motion must be authenticated." Foreword Magazine, Inc. v. OverDrive, Inc., 2011 WL 5169384, at *2 (W.D. Mich. Oct. 31, 2011). "The objection now 'contemplated by the amended Rule is not that the material 'has not' been submitted in admissible form, but that it 'cannot' be.'" Brown v. Siemens Healthcare Diagnostics, Inc., 2012 WL 3136457 at *5 (D. Md. 2012) (citation omitted, collecting cases). Thus, for example, while "'[t]he general rule is that inadmissible hearsay cannot be considered on a motion for summary judgment,' . . . 'a district court may consider a hearsay statement in passing on a motion for summary judgment if the statement could be reduced to admissible evidence at trial or reduced to admissible form.'" Jones v. UPS Ground Freight, 683 F.3d 1283, 1293-94 (11th Cir. 2012) (citation omitted).

Having undertaken the laborious chore of considering each of the many objections raised, and the responses and replies thereto, the Court finds that the challenged evidence is admissible as presented, and/or accepts RyMed's representation that the challenged evidence can be presented in

a form which is admissible at trial. Accordingly the objections will be overruled,[2] with only a few observations.

The majority of objections are based upon the simple assertion that a witness lacks personal knowledge and/or a foundation for the statement presented, yet each affiant (or declarant) states that he or she has personal knowledge of the statements made in the affidavit (or declaration). The Court has little basis at this point to doubt such representations, and is not in a position to rule whether or not an affiant (or declarant) knows of what he or she speaks. That, together with whether they have a foundation for their statements, is a matter that can only be made definitively at trial.

ICU also challenges many statements as being inconsistent with deposition testimony. But this alone is not a basis for exclusion, unless the affidavit is injected in an attempt to create a sham issue of fact. See, Aerel, S.R.L. v. PCC Airfoils, L.L.C., 448 F.3d 899, 908-09 (6th Cir. 2006).

ICU additionally objects to the entirety of the affidavit of David P. Gordon, an attorney in the Delaware action, on the grounds that he has not been a designated expert in this matter. This is too broad of an objection because, as ICU concedes in its reply, the date a patent expires is a factual matter on which expert testimony is not necessary. To the extent that Gordon also opines about what the patents cover, this seems to be something which can be discerned from the patent itself, a proper matter for judicial notice. See, Carlucci v. Han, ___ F. Supp.2d ___, ___, 2012 WL 3242618 at * 14 (E. D. Va., Aug. 7, 2012) ("Patents are generally considered matters of public record subject to judicial notice). Likewise, ICU's objection to RyMed's reliance on documents filed in the California litigation is not well-taken because the Court "may take judicial notice on its own" Fed.

[2] Obviously, this ruling is limited to consideration of the pending Motions for Summary Judgment, and the parties can raise any appropriate objections at trial.

R. Evid. 201(c)(2) of other court proceedings. See, Lynch v. Leis, 382 F.3d 642, 648 n.5 (6th Cir. 2004) ("as they are court records, this court may take judicial notice of them").

ICU also raises several objections to statements contained in the affidavits or declarations because they allegedly misrepresent certain advertisements therein. Since ICU concedes that the advertisements "speak for themselves," the advertisements themselves (absent some other objection) may be considered on summary judgment.

Sometimes its is easy to miss the forest for the trees, and it could be, given the sheer volume of objections, that some of the evidence relied upon in support of RyMed's positions are not admissible as presented, or may not be made admissible at trial. However, it is clear that there are many genuine issues of material fact requiring trial, and the Court can ferret out the inadmissible evidence at the bench trial in this case. Accordingly, the Court turns to the merits of the Motions for Summary Judgment.

IV. RYMED'S MOTION FOR PARTIAL SUMMARY JUDGMENT

ICU asserts two counterclaims against RyMed: (1) federal unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and (2) unfair and deceptive acts and practices under the Tennessee Consumer Protection Act ("TCPA"), Tenn. Code Ann. § 47-18-101, et seq. That the counterclaims are only two in number is deceptive as to their scope because ICU seeks wide ranging declaratory and injunctive relief, including that (1) RyMed be enjoined from violating the Lanham Act and the TCPA in relation to 26 specific statements, (First Amended Answer and Counterclaims, Docket No. 40, Sec. IV, ¶¶ 1 a. - y.); (2) it be prohibited from committing three specified acts or practices which allegedly violate those statutes (id. ¶¶ 2 a. - c.); and (3) that the Court declare that RyMed has violated the TCPA in relation to 24 of the statements (id. ¶¶ 3 a. - w.) and the three acts

or practices (id. ¶¶ 4 a. -c.) for which ICU seeks injunctive relief. Nevertheless, RyMed seeks summary judgment with respect to the majority of those statements, acts or practices because it has made a Rule 68 offer of judgment, some of the challenged statements were isolated, and/or the claims should have been asserted in the California action.

A. Rule 68 Offer of Judgment

RyMed sent ICU a letter dated November 28, 2011, indicating that it was desirous of resolving many of the issues in this case and was willing to meet ICU "more than halfway" and "resolve many, if not all, of the issues in this litigation by agreeing not to make the statements in question or by modifying the statements." (Docket No. 96-1 at 1) The letter contains a chart which tracks the sub-paragraphs of ICU's request for declaratory or injunctive relief, and sets forth RyMed's proposal or offer with respect to each one.

Rule 68 provides that "a party defending against a claim may serve on an opposing party an offer to allow judgment on specified terms, with the costs then accrued," and that "[i]f the judgment that the offeree finally obtains is not more favorable than the unaccepted offer, the offeree must pay the costs incurred after the offer was made." Fed. R. Civ. P. 68 (a) & (d). "The plain purpose of Rule 68 is to encourage settlement and avoid litigation." Marek v. Chesny, 473 U.S. 1, 5 (1985).

"To effectuate the purposes of Rule 68, an offer of judgment 'must specify a definite sum or other relief for which judgment may be entered and must be unconditional,'" so that a "plaintiff know[s] unequivocally what is being offered in order to be responsible for refusing such offer." Warren v. Sessoms & Rogers, P.A., 676 F.3d 365, 370-71 (4th Cir. 2012) (citation omitted) (collecting authorities). General contract principles are utilized to interpret Rule 68 offers of judgment, Andretti v. Borla Performance Industries, Inc., 426 F.3d 824, 837 (6th Cir. 2005), and

"an offer of judgment that satisfies a plaintiff's entire demand moots the case." O'Brien v. Ed Donnelly Enterprises, Inc., 575 F.3d 567, 574 (6th Cir. 2009).

Here, while RyMed has agreed to make many concessions for which it is to be applauded, it has not provided ICU with a typical offer of judgment because it falls short of satisfying ICU's entire demands, and leaves at least five statements indisputably still at issue. Further, with respect to some of the portions of the offer, RyMed agrees to stop making certain statements or taking certain actions only if ICU does the same, and RyMed agrees only to stop engaging in practices as currently performed, or agrees to stop making certain statements if allowed to make alternative statements. While RyMed cites cases for the proposition that an offer of judgment can include less than all claims, ICU's *claims* are two-fold - consisting of alleged violations of the Lanham Act and the TCPA, of which all of the statements are but a part.

That said, and recognizing that this case is set for a bench trial, the Court has no intention of deciding any issues that truly are not in dispute. Instead, the Court focuses on those five or so statements or acts that appear to be genuinely in dispute.

B. The California Action

In the California Action, RyMed sued ICU for false advertising and trademark infringement. With regard to the false advertising claims, RyMed claimed that many of ICU's statements about the InVision-Plus® violated the Lanham Act, and challenged ICU's "Critical Differences" document, which concerned coring, off-label use, microbial integrity, functional integrity, and leaking; an "ICU Assessment" document, which concerned leaking, product trials, incompatibility issues, and patent infringement; and, ICU's distribution of an FDA warning letter and related

statements about a RyMed product recall.[3]

At the time ICU filed is final amended counterclaim in the California action, RyMed was making the following four statements about the InVision-Plus® that ICU challenges in this litigation: (1) "The InVision-Plus® has a 'double microbial barrier'"; (2) "The tightness of the InVision-Plus® septum against the fluid spike provides additional protection against microbial contamination"; (3) "The InVision-Plus® reduces CRBSIs"; and (4) "The InVision-Plus® has zero fluid displacement upon connection and/or disconnection." RyMed insists that those claims are barred by res judicata because they should have been raised as counterclaims in the California action.

"For res judicata to apply, the following elements must be present: (1) a final decision on the merits by a court of competent jurisdiction; (2) a subsequent action between the same parties or their 'privies'; (3) an issue in the subsequent action which was litigated or which should have been litigated in the prior action; and (4) an identity of the causes of action." Bragg v. Flint Bd. of Educ., 570 F.3d 775, 776 (6th Cir. 2009) (citation omitted). "The party asserting the defense of res judicata bears the burden of proof." Winget v. JP Morgan Chase Bank, 537 F.3d 565, 572 (6th Cir. 2008).

The failure to file a counterclaim in a previous action may or may not bar raising the claim in a subsequent action, depending upon whether it was a compulsory or permissive counterclaim in the prior action. As has been explained:

> . . . [T]he "failure to interpose a counterclaim does not necessarily act as a bar to later actions." . . . There are two "exceptions" which lead to a later action being barred by res judicata: (1) compulsory counterclaims may be barred, and (2) permissive counterclaims too may be barred when "the relationship between the counterclaim

[3] ICU did not challenge any advertising by RyMed in the California action, but did assert counterclaims seeking cancellation of RyMed's "neutral" and "neutral displacement" trademarks.

> and the plaintiff's claim is such that the successful prosecution of the second action would nullify the initial judgment or impair the rights established in the initial action." . . . That is, res judicata may generally bar compulsory counterclaims, but not always permissive ones; otherwise res judicata would swallow Rule 13. But if allowing a permissive counterclaim to go forward would nullify the earlier judgment or impair rights established in the earlier action, even a permissive counterclaim can be barred.

Capitol Hill Group v. Pillsbury, Winthrop, Shaw, Pittman, LLC, 569 F.3d 485, 492 (D.C. Cir. 2009); see, Mitchell v. CB Richard Ellis Long Term Disab. Plan, 611 F.3d 1192, 1201 (9th Cir. 2010) ("where a party has failed to plead a compulsory counterclaim, the claim is waived and the party is precluded by principles of res judicata from raising it again"); Critical-Vac Filtration Corp. v. Minuteman Int'l, Inc., 233 F.3d 697, 699 (2nd Cir. 2000) ("[i]f a party has a compulsory counterclaim and fails to plead it, the claim cannot be raised in a subsequent lawsuit").

Under the Federal Rules of Civil Procedure, a compulsory counterclaim "arises out of the transaction or occurrence that is the subject matter of the opposing party's claim," while a permissive counterclaim is any counterclaim "that is not compulsory." Fed. R. Civ. P. 13(a) & (b). The Sixth Circuit applies "the 'logical relationship' test in determining whether a claim is a compulsory counterclaim." Central West Virginia Energy Co. v. Wheeling-Pittsburgh Steel Corp., 245 Fed. Appx. 415, 424 (6th Cir. 2007). "[U]nder that test, "the court 'determine[s] whether the issues of law and fact raised by the claims are largely the same and whether substantially the same evidence would support or refute both claims.'" Id. (quoting, Sanders v. First Nat'l Bank & Trust Co. in Great Bend, 936 F.2d 273, 277 (6th Cir. 1991). The "logical relationship" test "is necessarily flexible" because "'[a] court should consider the totality of the claims, including the nature of the claims, the legal basis for recovery, the law involved, and the respective factual backgrounds.'" Board Of Regents of University Of Wisconsin System v. Phoenix Intern. Software, Inc., 653 F.3d

448, 470 (7th Cir. 2011) (citation omitted).

RyMed argues the four statements relating to InVision-Plus® "arose out of the same core of operative facts as RyMed's claim for false advertising in the California action" because an issue there "was whether statements about the InVision-Plus were accurate descriptions of its design and performance." (Docket No. 86 at 16). RyMed also observes that "[t]he court in the California Action spent significant time and resources familiarizing itself with the InVision-Plus, the applicable science, and the needle-less IV connectors industry." Id.

A salutary purpose of the "logical relationship" test is that it serves the interest of judicial economy and efficiency. Maddox v. Kentucky Finan. Co., Inc., 736 F.2d 380, 383 (6th Cir. 1987); see, Southern Construction Co. v. Pickard, 371 U.S. 57, 60 (1962) (purpose of Rule 13(a) is "to prevent multiplicity of actions and to achieve resolution in a single lawsuit of all disputes arising out of common matters"). Thus, a "logical relationship" may be said to exist where separate trials on each of the claims would "'involve a substantial duplication of effort and time by the parties and the courts.'" Transamerica Occidental Life Ins. Co. v. Aviation Office of Amer., Inc., 292 F.3d 384, 390 (3rd Cir. 2002) (citation omitted). "Such a duplication is likely to occur when claims involve the same factual issues, the same factual and legal issues, or are offshoots of the same basic controversy between the parties." Id.

Having considered the record and the arguments of the parties, the Court finds that the statements at issue here were not compulsory counterclaims in the California case such that they are barred by the res judicata doctrine.[4] No doubt the judge in the California action went to school on

[4] This finding necessarily resolves RyMed's alternative argument that the false advertising claims are waived "'because the waiver or estoppel theory allows more discretion not to hold the claim is barred where to do so is manifestly unjust.'" Kane v. Magna Mixer Co., 71 F.3d 555, 562 (6th Cir. 1995) (citation omitted).

the needless intravenous connector industry and the related technology, but, given the myriad of claims that have been raised in this case, it seems certain that this Court, too, will be similarly educated.

Although, Rymed argues that part of "the essence of both lawsuits is whether statements made about the InVision-Plus®," (Docket No. 130 at 5), the maker of the statements is different. In the California Action, RyMed was pursuing claims for statements allegedly made by ICU about the InVision-Plus®, whereas, in this case, ICU is pursuing counterclaims for statements made by RyMed about the InVision-Plus® and about ICU's products. This is significant from an evidentiary perspective because, to establish a false advertising claim under the Lanham Act, a plaintiff must show that the advertisement tends to deceive a substantial audience and a causal link between the statement and harm, both of which relate to causation. American Council of Certified Podiatric Physicians v. Amer. Bd. or Podiatric Surgery, 185 F.3d 606, 613 (6th Cir. 1999).

This statements in this case, and those in the California action involve different advertising pieces and it is apparent that different evidence would be required to support or refute each false advertising claim at issue in the two actions. Evidence showing the circumstances under which each of the advertisements was made or distributed, the identity of persons who may have received the advertisements, the identity of persons who may have provided or made the advertisements to the relevant purchasing public, the identity of persons who may have been deceived by the advertisements, in what way the advertisements were deceiving, the identity of persons who may have been influenced in their purchasing decisions by the advertisements, and how the

advertisements influenced their purchasing decisions would all presumably be different.[5]

Accordingly, the Court finds that res judicata does not bar ICU's claims in this case.

V. ICU'S MOTIONS FOR SUMMARY JUDGMENT

RyMed's Second Amended Complaint is in four counts. ICU has filed a Motion for Summary Judgment with respect to Counts II and III, and a separate Motion for Summary Judgment directed to Counts I and IV, which also form the basis of ICU's First Amended Counterclaims. To provide context for the arguments, and to avoid redundancy, the Court first sets forth the governing substantive law applicable to both motions.

The Lanham Act was intended to make actionable the deceptive and misleading use of marks and to protect persons engaged in . . . commerce against unfair competition." Two Pesos, Inc. v. Taco Cabana, Inc., 505 U.S. 763, 767–68, 112 S.Ct. 2753, 120 L.Ed.2d 615 (1992) (internal citation marks omitted). "While much of the Lanham Act addresses the registration, use, and infringement of trademarks and related marks, § 43(a), 15 U.S.C. § 1125(a) is one of the few provisions that goes beyond trademark protection." Dastar Corp. v. Twentieth Century Fox Film Corp., 539 U.S. 23, 28–29, 123 S.Ct. 2041, 156 L.Ed.2d 18 (2003). In relevant part, that section provides:

> (1) Any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which—
>
> * * *
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

"To state a cause of action for misleading advertisement under the Lanham Act, a plaintiff

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[5] The fact that the statements were permissive counterclaims in the California does not bar their assertion here. There is no indication that successful prosecution of the claim in this case would nullify anything decided in the California action or impair rights established in that case.

must establish the following: 1) the defendant has made false or misleading statements of fact concerning his own product or another's; 2) the statement actually or tends to deceive a substantial portion of the intended audience; 3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions; 4) the advertisements were introduced into interstate commerce; and 5) there is some causal link between the challenged statements and harm to the plaintiff." American Council of Certified Podiatric Physicians and Surgeons v. American Bd. of Podiatric Surgery, Inc., 185 F.3d 606, 613 (6th Cir. 1999).[6]

A false or misleading statement may be "literally false" as an "unambiguous statement of fact," or "true yet misleading or confusing." Id. at 614. A statement can be misleading if it is "literally true, yet deceptive, or too ambiguous to support a finding of 'literal falsity,'" and, for purposes of injunctive relief, a plaintiff need only show "that the defendant's representations about its product have a tendency to deceive consumers." Herman Miller, Inc. v. Palazzetti Imports and Exports, Inc., 270 F.3d 298, 323 (6th Cir. 2001).

Generally, there are two types of statements "which, if false, may give rise to a cause of action: (1) bald assertions (e.g., "My product is better than yours"); and (2) assertions supported by testing (e.g., "Tests prove my product is better than yours")." EFCO Corp. v. Symons Corp., 219 F.3d 734, 739 -740 (8th Cir. 2000). "'[W]here a defendant's advertisement contends that clinical

[6] "To state a claim under the TCPA a plaintiff must show (1) the defendant engaged in an unfair or deceptive act or practice declared unlawful by the TCPA, and (2) the defendant's conduct caused an 'ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated[.]'" ProductiveMD, LLC v. 4UMD, LLC, 821 F.Supp.2d 955, 967 (M.D. Tenn. 2011) (quoting, Tenn.Code Ann. § 47–18–109(a)). A deceptive act or practice declare unlawful by the TCPA is "[d]isparaging the goods, services or business of another by false or misleading representations of fact," Tenn.Code Ann. § 47-18-104(b)(8) (2007), and this is Tennessee's state law equivalent of a Lanham Act claim. Medison America, Inc. v. Preferred Medical Systems, LLC,, 548 F. Supp.2d 567, 585 (W.D. Tenn. 2007).

tests' prove the superiority of its product. . . , the plaintiff need only prove that 'the tests referred to . . . were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited.'" Federal Express Corp. v. United Parcel Service, Inc., 765 F. Supp.2d 1011, 1018 (W.D. Tenn. 2010) (Federal Express II) (collecting cases, citations omitted). "On the other hand, where a superiority claim does not purport to rest on test results, the plaintiff may prove falsity 'only by adducing evidence that affirmatively show[s] [defendant's] claim ... to be false.'" Id.

"[M]ateriality is defined in terms of a statement's propensity to have some effect on consumers' purchasing decisions." Federal Express Corp. v. United States Postal Serv., 40 F. Supp.2d 943, 956 (W.D. Tenn. 1999) (Federal Express I). Whether a statement is material is something that "must be viewed in the light of the overall context in which it appears." Pizza Hut, Inc. v. Papa John's Intern., Inc., 227 F.3d 489, 495 n.5 (5th Cir. 2000).

A. Motion for Summary Judgment on Counts II and III of the Second Amended Complaint

ICU seeks summary judgment on RyMed's assertion in Counts II and III of the Second Amended Complaint that the following constitute false advertising:

> (1) A document entitled, "Needlefree Connectors - Comparative Matrix" (the "Comparative Matrix");
>
> (2) A statement from ICU's website that the CLAVE® "provides the only completely internal fluid path in a needlefree system";
>
> (3) A photograph of ICU's MicroCLAVE® that does not show a "gap" around the septum;
>
> (4) ICU's statement that "the CLAVE® demonstrates the best barrier to bacterial transfer compared to all connectors";
>
> (5) ICU's statement that the CLAVE® is the "world's leading needlefree connector and has been proven to have a lower incidence of CRBSI";

(6) ICU's statement that a website animation demonstrates "the ability of the CLAVE to prevent contamination of the fluid path";

(7) ICU's statement that the CR-BSI rate at a hospital decreased by 49% when the CLAVE® was re-introduced;

(8) A poster prepared by Dr. Marcia Ryder comparing ICU's MicroCLAVE® to five competitors; and

(9) ICU's statement that the CLAVE® is the "only connector proven to reduce bacterial colonization of the catheter and bloodstream infections."

In response, RyMed asserts that because it is seeking injunctive relief, and because ICU has discontinued making certain statements or representation, RyMed does not object to summary judgment being entered on claims (1) – (3) as set forth above. Additionally, RyMed "does not dispute that the part of the statement that the CLAVE® is the "world's leading needlefree connector is puffery." (Docket No. 110 at 5 n.19).[7] Accordingly, summary judgment will be granted with respect to those statements.[8] Prior to discussing the remaining statements, the Court briefly addresses an evidentiary issue raised by ICU.

ICU argues that RyMed attempts to create a triable issue of fact "through purported 'expert testimony' regarding purported flaws in ICU's cited scientific studies by its attorney (Michael Abelow) and Director of Marketing (Scott Chase)." (Docket No. 125 at 2). ICU observes that RyMed has failed to retain any experts in this case "and cannot now cure that failure by submitting

[7] Mere puffery is not actionable under the Lanham Act. Interactive Products Corp. v. a2z Mobile Office Solutions, Inc. 326 F.3d 687, 699 (6th Cir. 2003).

[8] Because summary judgment will be granted on the "Comparative Matrix" statement, the Court deems RyMed's Motion for Review and Motion to Stay moot, since both motions relate to Magistrate Judge Bryant's ruling that RyMed supplement its response ICU's Interrogatory 6 which sought the identity of the Bon Secours manager who provided the "Comparative Matrix" to RyMed. If ICU concludes that it still needs the identity of this individual with respect to any remaining claims in this lawsuit, it can re-raise the issue with Judge Bryant.

as 'expert testimony' the law testimony of [those] non-experts[.]"

The Court does not view the affidavits from Abelow and Chase as being an attempt to introduce expert testimony. Rather, those affiants identify evidence which has been taken in this case (such as depositions), and studies which purport to support RyMed's assertions.[9] With regard to ICU's statement 4 that the "CLAVE® demonstrates the best barrier to bacterial transfer compared to all connectors," RyMed has pointed to evidence which could be interpreted to suggest that ICU did not disclose in the statement that it funded the studies upon which the statement was based, that the study skipped the clinical step of disinfecting the connector, and other studies show significant problems with bacterial transfer in the CLAVE®.[10] As for (1) the portion of statement 5 that the CLAVE® has been proven to have a lower incidence of CRBSIs, (2) statement 7 that the CRBSI rate at a hospital decreased by 49% when the CLAVE® was re-introduced, and (3) statement 9 that the CLAVE® is the "only connector proven to reduce bacterial colonization of the catheter and bloodstream infections," Rymed has pointed to evidence that suggests the studies upon which those statements were based – the Maragakis and Moore studies – may have methodological flaws that impact on their reliability.

"The few courts that have addressed false advertising claims involving 'reports' of studies

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[9] Whether those studies will come in at trial is, of course, a matter to be determined at that time.

[10] The Court is unpersuaded (based solely on the summary judgment record) by ICU's alternative argument that the statement "best barrier" is mere puffery and not properly the subject of a Lanham Act claim. While statements like "world's best" can be non-actionable puffery, see, City of Monroe Emps. Ret. Sys. v. Bridgestone Corp., 399 F.3d 651, 671 (6th Cir.2005), false advertising claims must be viewed in context. Here, the "best barrier" statement is made in the context of the assertion that ICU's connector is the best as compared to all connectors, and the Ryder poster is specifically cited as support for that assertion. See, Newcal Indus., Inc. v. Ikon Office Solution, 513 F.3d 1038, 1053 (9th Cir. 2008) ("Ultimately, the difference between a statement of fact and mere puffery rests in the specificity or generality of the claim," and "[a] statement is considered puffery if the claim is extremely unlikely to induce consumer reliance.").

or surveys have treated such 'reports' as establishment claims," meaning that the plaintiff need only prove that the test " were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition for which they were cited.'" Federal Express II, 765 F. Supp.2d at 1018. "What makes a test or study 'sufficiently reliable to permit one to conclude with reasonable certainty that [the test] established the proposition for which it was cited'" is an open question, "but the notion appears to be tied to whether the methods and findings of the cited study are acceptable to the relevant scientific community." Riddell, Inc. v. Shutt Sports, Inc., 742 F.Supp.2d 963, 972 (W.D. Wis. 2010) (citation omitted). As ICU concedes, "[r]eliability concerns can include a high margin of error, an insufficient sample size, insufficient screening of participants, excessively narrow questions and responses, or flaws in the structure execution and methodology of the study." (Docket No. 79 at 11, citing, Federal Express II, 765 F.Supp.2d at 1020).

"Usually, objections based on flaws in the survey's methodology are properly addressed by the trier of fact," PBM Prod., LLC v. Mead Johnson & Co. , 639 F.3d 111, 123 (4th Cir. 2011), and so, too, here. The Maragakis study is allegedly flawed because it compared the CLAVE® to a positive-pressure mechanical device which, apparently, has known infection problems according to the FDA. The Moore study is allegedly flawed because it compared the CLAVE® to an anonymous luer activated device, the "academic medical center" utilizing the CLAVE® contemporaneously improved compliance with hand hygiene protocol and implemented a central line bundle, thereby calling into question what actually caused the reduction in CRBSIs. That is something to be explored at trial.[11]

[11] In determining that questions of fact exist regarding the reliability of the studies, the Court fully recognizes that "[t]o ensure vigorous competition and to protect legitimate commercial speech, courts applying [the sufficiently reliable] standard should give advertisers a fair amount of leeway, at least in the absence of a clear intent to deceive or substantial consumer confusion." Rhone-Poulenc Rorer Pharm., Inv.

Likewise, the Court denies summary judgment with respect to statement 8, which is a 2011 poster that compares the MicroCLAVE® to five competitors. While the chart in the poster does indicate that it is dividing statistically distinct groups by color, and even accepting that RyMed's InVision-Plus® placement as last in the chart was due to the fact that it was among the worst performing product with respect tomean log density, the record is murky as to whether the study upon which it is based is reliable. Both parties cite deposition testimony from Dr. Marcia Ryder (Docket No. 112-14 at pp. 180-189), but the Court is not in a position to conclusively rule as to what that testimony means.

Finally, the Court will grant summary judgment with respect to statement number 6, which relates to a statement in a website animation, that it demonstrates the ability of the CLAVE® to prevent contamination of the fluid path. While RyMed claims the demonstration proves no such thing, that is not the assertion. Rather the assertion is that the animation *demonstrates* how the CLAVE® has the ability to prevent contamination, and that is something that the viewer can accept or reject based upon viewing the demonstration. Moreover, RyMed has wholly failed to show that any consumers were confused by the website animation.

B. Motion for Summary Judgment on Counts I and IV of the Second Amended Complaint and the First Amended Counterclaims

This Motion is directed at both counts of ICU's First Amended Counterclaims and Counts I and IV of RyMed's Second Amended Complaint, all of which are related to advertisements or statements made by RyMed on its website and at seminars and trade shows. Some of the arguments raised in support and opposition to this motion have been discussed previously, such as the effect

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Marion Merrell Dow, Inc., 93 F.3d 511, 515 (8th Cir. 1996).

of the Rule 68 Offer of Judgment, and the statement raised relating to the impact of the Delaware action.

The statements that appear to actually require a ruling at this point,[12] include (1) RyMed's zero displacement claim; (2) its claim that the InVision-Plus® reduces CRBSIs; (3) its claims that the InVision-Plus® has a double microbial barrier and that the tightness of the InVision-Plus® septum provides additional protection; and (4) its "superiority" claims based upon alleged scientific support.[13]

RyMed touts the InVision-Plus® as having zero fluid displacement upon connection and disconnection. RyMed supports this claim by pointing to a Nelson Laboratories Report that showed that the overall mean fluid displacement upon attachment for all 55 of the tests performed on the InVision-Plus® was +0.0022 mL, but also showed 0.000 mL fluid movement in 39 out of the 55 times that the product was tested. Similarly, the overall mean fluid displacement upon detachment was shown to be -0.0002 mL, but also shown to have exactly 0.000 mL fluid movement in 48 out of the 55 times it was tested upon detachment.

Given these results, fair arguments can be made that the zero claim is true or false, depending upon whether zero means exactly zero, whether something can effectively be zero when

[12] The Court uses the phrase "appear to" because, although RyMed claims that its Rule 68 offer mooted the majority of ICU's claims and does not argue those "mooted" claims in relation to other motions, RyMed does argue that triable issues of fact exist as to some of the claims addressed by this motion that it contends are now moot. This includes, by example, whether RyMed's displacement videos and demonstrations, which purport to show zero displacement, are based on a "circus trick." As noted early-on in this decision, the Court does not intend to address matters that have been, or seem to be, easily resolved by the parties. If it is necessary to address any of the statements for which a true offer of judgment has been made, the Court will do so at the bench trial in this case.

[13] With respect to the items (2) and (4), RyMed has agreed to stop making statements or engaging in the challenged conduct, only to the extent that ICU agrees to do the same.

only non-zero digits occur several places to the right of the decimal point, and/or whether something can be characterized as zero when many tests show absolute zero while other tests show something very close to it. Having reviewed the evidentiary material proffered by the parties, and considering the parties' apparent agreement that there is no standard in the medical device community for what zero means, the Court concludes that genuine issues preclude summary judgment because even Alison Bucar, ICU's corporate designee, testified in his deposition that a "true zero in fluid dynamics is pretty much impossible," and appears to have reluctantly conceded that it is not necessarily improper to round .015 or .02 to zero since there is no appreciable difference. (Docket No. 112-10 at pp. 101 & 104-105).

In addition to touting zero fluid displacement, RyMed's claims that its InVision-Plus® reduces CRBSIs, and part of the reason for that is the tightness of the septum and the fact that it has a double microbial barrier. In support of its position, RyMed points to five articles. In response, ICU argues that the articles are not reliable because four of the five were authored by paid RyMed consultants, only two of the articles actually report anything about CRBSI rates, and the best any of the articles do is support a "supposed association" between use of the InVision-Plus® and lower CRBSIs. However, and leaving aside that ICU, too, relies upon paid consultants (such as Dr. Ryder) for marketing material, the issues that ICU raises in relation to the articles goes to their weight.

Finally, the Court will deny summary judgment on ICU's assertion that "RyMed engages in false advertising by creating and financing marketing promotional articles and posters regarding the InVision that masquerade as research by independent scientists and practitioners." (Docket No. 82 at 14). This argument is undeveloped by ICU in terms of the extent to which a failure to disclose is actionable as a claim under the Lanham Act, and whether there are generally applicable disclosure

standards in the field. The Court will consider the proof and legal arguments on this issue at the trial in this matter.

VI. CONCLUSION

Based upon the foregoing, RyMed's Partial Motion to Dismiss will be granted; ICU's Objections will be overruled and its Motion to Strike will be denied; RyMed's Motion for Partial Summary Judgment will be denied; ICU's Motion for Summary Judgment on Counts II and III of RyMed's Second Amended Complaint will be granted in part; ICU's Motion for Summary Judgment on First Amended Counterclaims (and Counts I and IV of RyMed's Second Amended Complaint) will be denied; and RyMed's Motions for Review and to Stay will be deemed moot.

An appropriate Order will be entered.

Kevin H. Sharp

KEVIN H. SHARP
UNITED STATES DISTRICT JUDGE